the stock solution with solution 3 to the reference concentration of 1.0 microgram of erythromycin base per milliliter (estimated).

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(3) *pH.* Proceed as directed in § 436.202 of this chapter, except standardize the pH meter with pH 7.0 and pH 10.0 buffers and prepare the sample as follows: Dissolve 200 milligrams of sample in 5 milliliters of reagent grade methyl alcohol. Add 95 milliliters of water and mix. Record the pH when an equilibrium value has been reached.

(4) *Residue on ignition.* Proceed as directed in § 436.207(a) of this chapter.

(5) *Identity test.* Proceed as directed in § 436.211 of this chapter, using the sample preparation method described in paragraph (b)(3) of that section.

(6) *Crystallinity.* Proceed as directed in § 436.203(a) of this chapter.

[51 FR 35213, Oct. 2, 1986, as amended at 55 FR 11584, Mar. 29, 1990; 55 FR 25392, June 21, 1990]

PART 453—LINCOMYCIN ANTIBIOTIC DRUGS

Subpart A—Bulk Drugs

Subpart B—Oral Dosage Forms

Subpart C—Injectable Dosage Forms

Subparts D–E—[Reserved]

Subpart F—Dermatologic Dosage Forms

AUTHORITY: Sec. 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

Subpart A—Bulk Drugs

§ 453.20 Clindamycin hydrochloride hydrate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Clindamycin hydrochloride hydrate is the hydrated hydrochloride salt of clindamycin. It is so purified and dried that:

(i) Its clindamycin content is not less than 800 micrograms of clindamycin per milligram.

(ii) Its microbiological activity is not less than 800 micrograms of clindamycin per milligram.

(iii) [Reserved]

(iv) Its moisture content is not less than 3.0 percent and not more than 6.0 percent.

(v) Its pH in an aqueous solution containing 100 milligrams per milliliter is not less than 3.0 and not more than 5.5.

(vi) It is crystalline.

(vii) It passes the identity test for clindamycin hydrochloride hydrate.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5(b) of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for clindamycin content, microbiological activity, moisture, pH, crystallinity, and identity.

(ii) Samples required: 10 packages, each containing approximately 300 milligrams.

(b) *Tests and methods of assay*—(1) *Clindamycin content* (*vapor phase chromatography*). Proceed as directed in § 436.302 of this chapter.

(2) *Microbiological activity* (*microbiological agar diffusion assay.*)

Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample in sufficient sterile distilled water to give a stock solution of convenient concentration. Further dilute the stock solution with 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to the reference concentration of 1.0 microgram of clindamycin per milliliter (estimated).

(3) [Reserved]

(4) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(5) *pH.* Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 100 milligrams per milliliter.

(6) *Crystallinity.* Proceed as directed in § 436.203 of this chapter.

(7) *Identity.* Proceed as directed in § 436.211 of this chapter, using the sample preparation method described in paragraph (b)(2) of that section.

[39 FR 19161, May 30, 1974, as amended at 50 FR 19921, May 13, 1985]

§ 453.21 Clindamycin palmitate hydrochloride.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Clindamycin palmitate hydrochloride is the white to off-white amorphous powder of the hydrochloride salt of the palmitic acid ester of clindamycin. It is freely soluble in water, ethanol, chloroform, and ether. It is so purified and dried that:

(i) It contains not less than 540 micrograms of clindamycin per milligram.

(ii) [Reserved]

(iii) Its moisture content is not more than 3.0 percent.

(iv) Its pH in an aqueous solution containing 10 milligrams per milliliter is not less than 2.8 and not more than 3.8.

(v) It passes the identity test for clindamycin palmitate hydrochloride.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for clindamycin content, moisture, pH, and identity.

(ii) Samples required: 10 packages, nine containing not less than 300 milligrams and one package containing not less than 2 grams.

(b) *Tests and methods of assay*—(1) *Clindamycin content.* Proceed as directed in § 436.303 of this chapter.

(2) [Reserved]

(3) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(4) *pH.* Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 10 milligrams per milliliter.

(5) *Identity.* Proceed as directed in § 436.211 of this chapter, using the sample preparation method described in paragraph (b)(2) of that section.

[39 FR 19161, May 30, 1974, as amended at 50 FR 19921, May 13, 1985]

§ 453.22 Clindamycin phosphate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Clindamycin phosphate is a water-soluble ester of clindamycin and phosphoric acid. It occurs as a white to off-white powder. It is so purified and dried that:

(i) Its clindamycin content is not less than 758 micrograms of clindamycin per milligram calculated on an anhydrous basis.

(ii) Its microbiological activity is not less than 758 micrograms of clindamycin per milligram calculated on an anhydrous basis.

(iii) [Reserved]

(iv) Its moisture content is not more than 6.0 percent.

(v) Its pH in an aqueous solution containing 10 milligrams per milliliter is not less than 3.5 and not more than 4.5.

(vi) It is crystalline.

(vii) It passes the identity test for clindamycin phosphate.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain: